IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : John C. Smith et al.
Serial No. : 09/761,581
Filed : January 18, 2001
Title : METHODS

Art Unit : 1634
Examiner : Juliet C. Einsmann

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

Responsive to the action mailed September 26, 2002, please amend the application as follows.

In the claims:

Cancel claims 7, 9, and 10.

Add new claims 11-24.

--11. A method of performing a linkage study, the method comprising

a) providing a test sample from a subject; and

b) detecting a genetic marker in a PDH E1β nucleic acid, wherein the genetic marker is a polymorphism at one or more of the following positions: A457G, A1191C, C1198T, or C1342A as defined by the positions in SEQ ID NO:1.

12. A method of performing a bioinformatic analysis, the method comprising

a) providing a test sample from a subject;

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b) obtaining sequence information by detecting a polymorphism in a PDH E1β nucleic acid of the test sample, wherein the polymorphism is located at position 457, 1191, 1198, or 1342 as defined by the positions in SEQ ID NO:1;

c) storing the sequence information in a computer readable medium; and

d) analyzing the stored sequence information with a bioinformatics program or database.

13. The method of claim 12, wherein the bioinformatics program or database provides a means for homology searching, mapping, haplotyping, genotyping, or assessing pharmacogenetics.

14. A method of performing a bioinformatic analysis, the method comprising

a) providing a test sample from a subject;

b) obtaining sequence information by detecting a polymorphism in a PDH E1β nucleic acid of the test sample, wherein the polymorphism is A457G, A1191C, C1198T, or C1342A as defined by the positions in SEQ ID NO:1;

c) storing the sequence information in a computer readable medium; and

d) analyzing the stored sequence information with a bioinformatics program or database.

15. The method of claim 14, wherein the bioinformatics program or database provides a means for homology searching, mapping, haplotyping, genotyping, or assessing pharmacogenetics.

16. A method of performing a bioinformatic analysis, the method comprising

a) providing a test sample from a subject;

b) obtaining sequence information by detecting a haplotype in a PDH E1β nucleic acid of the test sample, wherein the haplotype is A457G, A1191C, C1198T, or C1342A as defined by the positions in SEQ ID NO:1;

c) storing the sequence information in a computer readable medium; and

d) analyzing the stored sequence information with a bioinformatics program or database.

17. The method of claim 16, wherein the bioinformatics program or database provides a means for homology searching, mapping, haplotyping, genotyping, or assessing pharmacogenetics.

18. A method of performing a bioinformatic analysis, the method comprising

a) providing sequence information obtained from a PDH E1β nucleic acid of a test sample, wherein the PDH E1β nucleic acid has a polymorphism located at position 457, 1191, 1198, or 1342 as defined by the positions in SEQ ID NO:1;

b) storing the sequence information in a computer readable medium; and

c) analyzing the stored sequence information with a bioinformatics program or database.

19. The method of claim 18, wherein the bioinformatics program or database provides a means for homology searching, mapping, haplotyping, genotyping, or assessing pharmacogenetics.

20. A method of performing a bioinformatic analysis, the method comprising

a) providing sequence information obtained from a PDH E1β nucleic acid of a test sample, wherein the PDH E1β nucleic acid has a polymorphism that is A457G, A1191C, C1198T, or C1342A as defined by the positions in SEQ ID NO:1;

b) storing the sequence information in a computer readable medium; and

c) analyzing the stored sequence information with a bioinformatics program or database.

21. The method of claim 20, wherein the bioinformatics program or database provides a means for homology searching, mapping, haplotyping, genotyping, or assessing pharmacogenetics.

22. A method of performing a bioinformatic analysis, the method comprising

a) providing sequence information from a PDH E1β nucleic acid of a test sample, wherein the PDH E1β nucleic acid has a haplotype that is 1191C, 1198C, 1342A; 1191A, 1198C, 1342C; or 1191C, 1198T, 1342A as defined by the positions in SEQ ID NO:1;

b) storing the sequence information in a computer readable medium; and

c) analyzing the stored sequence information with a bioinformatics program or database.

23. The method of claim 22, wherein the bioinformatics program or database provides a means for homology searching, mapping, haplotyping, genotyping, or assessing pharmacogenetics.

24. The method of claim 1, wherein the sequence is determined at all of the following nucleotide positions: 457, 1191, 1198, and 1342, as defined by the positions in SEQ ID NO:1.--

REMARKS

Claims 1-6, 8, and 11-24 are now pending in the application, claims 7, 9, and 10 having been cancelled and new claims 11-24 added by the above amendment. Support for new claim 11 can be found, *e.g.*, on page 6, lines 6-22; and page 14, lines 9-10. Support for new claims 12 and 18 can be found in claim 1 as originally filed and in the specification, *e.g.*, on page 4, lines 9-13; page 6, lines 17-22; page 15, lines 15-28; and page 16, lines 17-20. Support for new claims 14 and 20 can be found in claim 2 as originally filed and in the specification, *e.g.*, on page 6, lines 6-22; page 15, lines 15-28; and page 16, lines 17-20. Support for new claims 16 and 22 can be found in claim 3 as originally filed and in the specification, *e.g.*, on page 5, lines 3-6; page 6, lines 17-18; page 15, lines 15-28; and page 16, lines 17-20. Support for new claims 13, 15, 17, 19, 21, and 23 can be found, *e.g.*, on page 16, lines 21-22. Support for new claim 24 can be found in claim 1 as originally filed, as well as in the specification, *e.g.*, on page 6, lines 13-16. No new matter has been added.

Applicants elect the invention of Group I, drawn to a method for the diagnosis of a polymorphism using nucleic acid analysis and treatment of a disease. Further, applicants elect the single polymorphism at position 457 (A457G) according to the position in SEQ ID NO:1. This election, however, is made with traverse.

The Restriction Requirement correctly observes that many of the claims (including the elected claims) recite determining the sequence "at one or more" of the four nucleotide positions of the PDH E1β gene. Applicant points out that if the restriction requirement restricting the four polymorphisms to four separate groups is allowed to stand, it will limit applicants to claiming a method of determining the sequence at only a single one of the four positions. The restriction requirement ignores those embodiments of claim 1 in which the sequence at two, three, or four of the positions is determined. It essentially prohibits applicants from presenting claims limited to such embodiments in this application or any divisional. An example of such a claim is submitted as a new claim 24 above. As this claim is dependent on claim 1, it must be included in the elected group. However, it clearly will require examination of all four polymorphisms. Applicants fail to see how the restriction requirement, as presently formulated, can stand in view of new claim 24.

Applicants strongly protest and request withdrawal of the restriction requirement, at least with respect to restricting among the four polymorphisms. In addition, applicants request consideration of new claims 11-24.

Attached is a marked-up version of the changes being made by the current amendments.

Enclosed is a Petition for Extension of Time for two months and a check for the required fee of $400. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: Dec. 20, 2002

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